

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
CERVELLI, ROBERT C/O ORIGIN
BIOMEDICINALS INC.
5162 Duke Street
Suite 520
Halifax, Nova Scotia
Canada, B3J 1N7

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY,
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year) 04 February 2005 (04-02-2005)

Applicant's or agent's file reference

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No
PCT/CA2004/001659

International filing date (day/month/year) 21 September 2004 (21-09-2004)

Applicant ORIGIN BIOMEDICINALS INC. ET AL

- 1 ☒ [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ [] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ [] With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ [] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ [] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for the international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/CA
Commissioner of Patents
Canadian Patent Office
Box PCT, Ottawa/Gatineau K1A 0C9
Facsimile No.

Authorized officer
Lucille Leonard (819) 953-1737

NOTES TO FROM PCT/ISA/220

These Notes are intended to give instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)) :

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FROM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter :

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
CERVELLI, ROBERT C/O ORIGIN
BIOMEDICINALS INC.
 5162 Duke Street
 Suite 520
 Halifax, Nova Scotia
 Canada, B3J 1N7

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (date/month/year)	04 February 2005 (04-02-2005)
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Applicant's or agent's file reference	FOR FURTHER ACTION See paragraph 2 below		
International application n ^o PCT/CA2004/001659	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">International filing date (date/month/year) 21 September 2004 (21-09-2004)</td> <td style="width: 50%;">Priority date (date/month/year) 23 September 2003 (23-09-2003)</td> </tr> </table>	International filing date (date/month/year) 21 September 2004 (21-09-2004)	Priority date (date/month/year) 23 September 2003 (23-09-2003)
International filing date (date/month/year) 21 September 2004 (21-09-2004)	Priority date (date/month/year) 23 September 2003 (23-09-2003)		
International Patent Classification (IPC) or both national classification and IPC A61K7/48 A61K9/06 A61K35/78 A61P17/00			
Applicant ORIGIN BIOMEDICINALS INC.			

1. This opinion contains indications relating to the following items :

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA <i>Commissioner of Patents</i> <i>Canadian Patent Office</i> <i>Box PCT, Ottawa/Gatineau K1A 0C9</i>	Authorized officer <p style="text-align: right;">Ingrid Elder (819) 934-2327</p>
Facsimile No. (819) 953-9538	

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/001659

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language which it was filed, unless otherwise indicated under this item.

- ☐ This opinion has been established on the basis of a translation from the original language into the following language __, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/001659

Box No. V reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-17	NO
Inventive step (IS)	Claims		YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations :

Section V:

Reference is made to the following documents:

D1: US 6 150 422
D2: EP 0 755 673
D3: CA 2 353 071
D4: US 5 665 367
D5: CA 2 215 210
D6: CA 2 221 236

Novelty

D1 discloses a stable gelled composition in the form of a cream, an ointment or a paste, wherein said composition contains at least one lipophilic polyphenol active agent sensitive to oxygen and/or to water, such as flavonoids; a gelling agent, such as a gum; and a solvent, such as vegetable oils. D1 also discloses that the oily gel comprising the lipophilic agent is stable for prolonged storage use.

D3 discloses a topical composition comprising an active agent, such as dithranol; an oil body from plant cells, such as coconut oil and jojoba oil; and a gelling agent, such as cellulose and gums (page 16, lines 7-13).

Therefore having regards to D1 or D3, the subject-matter of claims 1, 2, 4, 8-10, 12, 16 and 17 is therefore not new (Article 33(2) PCT).

D2 discloses a stable topical application containing at least one water-sensitive active agent, such as green tea extract; a polyol, such as glycerol or glycols; and a vegetable oil, such as jojoba oil. D2 also discloses that the polyol in combination with the structuring agent (aka oil) prevents the degradation of the water-sensitive actives.

The subject-matter of claims 1, 2, 3, 8-10, 11, 16 and 17 is therefore not new (Article 33(2) PCT).

D4 discloses a skin conditioning composition comprising a flavonoid, a retinol and a cosmetically acceptable vehicle. Example 10 discloses a non-aqueous skin care composition comprising a gum and herbal oils.

The subject-matter of claims 1, 2, 4, 8, 10, 11, and 16 is therefore not new (Article 33(2) PCT).

see Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/001659

Box No. VIII

Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Section VIII:

Claims 1, 2, 10 and 12-15 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1, 2, 10 and 12-15 are indefinite due to the use of the term "suitable".

Claims 2 and 10 are objected to under Article 6 PCT. The subject matter in these claims is defined in terms of the results to be achieved and not the compounds that are actually used to carry out the invention. Such a functional definition does not distinctly and explicitly describe any particular compound or distinguish one compound from another, but rather serves only to define a family of compounds having a common function and not a structure, which serves to distinguish one compound from another. Thus the expression "absorbent binding carrier to which the polyphenol will bind for purposes of even disbursement within the cream, gel or ointment, and release on and into the skin when the cream, gel or ointment is applied thereof" does not define any particular kind of compounds but rather the effect that the desired compounds should possess.

Claims 4, 9, 12 and 17 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 4, 9, 12 and 17 are indefinite due to the use of the expression "but is not limited to".

Claims 9 and 17 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 9 and 17 are indefinite due to the use of the expression "such as".

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D6 is not mentioned in the description, nor are these documents identified therein.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/001659

Supplemental Box

Continuation of : _____

Section V:

Inventive Step

The distinguishing feature of claims 3 and 11 regarding the disclosure of D1 is that the polyphenol is derived from tea (*Camellia sinensis*) and green tea. D5 and D6 describe the incorporation of polyphenol extractions from tea (*Camellia sinensis*) and green tea into topical compositions. Accordingly, it would be obvious for the skilled person to include a polyphenol derived from tea (*Camellia sinensis*) and green tea into the topical composition of D1. Therefore, the subject-matter of claims 3 and 11 does not involve an inventive step (Article 33(3) PCT).

Dependent claims 5-7 and 13-15 do not contain additional technical features which might establish novelty and an inventive step over Articles 33(2) and 33(3) PCT due to the subject matter in the claims being known to someone skilled in the art. These claims are only allowable in combination with patentable independent claims.

Industrial Applicability

The claimed subject matter of claims 1-17 is considered to be industrially applicable and thus fulfilling the requirements of Article 33(4) PCT.

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